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Proposed Re-evaluation Decision PRVD2016-22

Antisapstain and Joinery Uses of Boron

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Background

This document forms part of a wider assessment of health and environmental risks of the active ingredients used in antisapstain and joinery wood treatments.

In 2004, Health Canada's Pest Management Regulatory Agency (PMRA) completed a re-evaluation of the occupational risks for the antisapstain uses of three antisapstain active ingredients: 2-(thiocyanomethylthio) benzothiazole (TCMTB), copper-8-quinolinolate (copper-8), and disodium octaborate tetrahydrate (boron). The occupational exposure and risk assessments were conducted for workers at lumber processing facilities such as sawmills. The re-evaluation decision (RRD2004-08) identified the need for additional data to refine the occupational risk assessments and required that a product stewardship program (with follow-up monitoring) be implemented for all registered antisapstain chemicals to reduce exposure to workers. In addition, RRD2004-08 indicated that an assessment of the environmental risks of antisapstain products would be communicated in separate documents.

In response to the 2004 decision, the registrants of antisapstain products, the Sapstain Industry Group, developed a product stewardship program, referred to as the Exposure Reduction Program (ERP). This program was approved by PMRA, implemented for all antisapstain products and follow-up occupational exposure field monitoring was conducted. The ERP included additional personal protective equipment and engineering controls, which have shown to be effective in reducing worker exposure.

There are currently five active ingredients registered as joinery wood preservatives. These active ingredients are: boron, didecyl dimethyl ammonium chloride (DDAC), iodocarb, propiconazole and tebuconazole. Considering that the occupational exposure scenarios for antisapstain and joinery uses are similar, and in the interest of efficiencies and consistency in decision making, occupational risk assessments were also conducted for all joinery products using the Sapstain Industry Group's follow-up field monitoring exposure data.

Altogether seven active ingredients registered as antisapstain and/or joinery wood preservatives required updated health and environmental risk assessments. These active ingredients are: TCMTB, copper-8, boron, DDAC, iodocarb, propiconazole, and tebuconazole. The occupational risk assessments for these seven antisapstain and joinery active ingredients have been updated using current use information, current toxicology endpoints and the follow-up field monitoring exposure data. The environmental risk assessments have been conducted using available data and information.

This document addresses the health and environmental risk assessments for the antisapstain and joinery uses of boron. The re-evaluation of the antisapstain and joinery uses of the remaining active ingredients listed above will be communicated in separate documents.

Overview

Proposed Re-evaluation Decision for Antisapstain and Joinery Uses of Boron

The PMRA has completed the health and environmental risk assessments for the antisapstain and joinery uses of boron. Under the authority of the *Pest Control Products Act*, the PMRA is proposing continued registration of the antisapstain and joinery uses of boron in Canada.

An evaluation of available scientific information found that the antisapstain and joinery uses of boron products are not expected to pose risks of concern to human health or the environment when used according to the proposed revised label directions. As a requirement for the continued registration of antisapstain and joinery products containing boron, new risk-reduction measures are proposed.

This proposal affects the joinery and antisapstain end-use products containing boron registered in Canada. Once the final re-evaluation decision is made, the registrant will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for boron and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of boron.

The PMRA will accept written comments on this proposal up to 90 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[2] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use of, or exposure to, the product under its conditions or proposed conditions of registration. Conditions of registration may include special precautionary measures on the product label to further reduce risk. The Act also requires that products have value[3] when used according to the label directions.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

3 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "... the product's actual or

To reach its decisions, the PMRA applies hazard and risk assessment methods as well as policies that are rigorous and modern. These methods consider the unique characteristics of potentially sensitive subpopulations in both humans (for example, children) and organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties present when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management section of Health Canada's website.

For more details on the information presented in this overview, please refer to the Science Evaluation of this consultation document.

What is Boron?

Boron is registered in Canada for the control of a broad range of insects and fungi in structures, wood and wood products as well as a material preservative. Boron inhibits reproduction of fungi by acting on the general metabolism, and act as a stomach poison in insects.

Antisapstain products are wood preservatives used to prevent the growth of staining fungi in freshly cut lumber. They are applied to freshly-cut wood by dipping or spraying to achieve short-term (months) protection against staining fungi.

Wood products that have been manufactured into items such as windows and doors are referred to as joinery or millwork. These items are often used in above-ground settings where they are subject to moderate decay conditions. For this reason, wooden windows and doors are typically protected with a joinery wood preservative to prevent the growth of decay fungi and increase the service life. Unlike antisapstain treatments, which are applied to lumber for short-term protection against aesthetic damage, joinery preservatives provide long-term decay protection to wood that does not require the degree of protection provided by heavy-duty wood preservation.

Health Considerations

Can Approved Uses of Boron Affect Human Health?

Antisapstain and joinery products containing boron are unlikely to affect your health when used according to revised label directions.

Boron is a naturally occurring substance and is ubiquitous in the environment (present in food, drinking water, air, soil, and dust). The most common source of exposure to boron is from environmental background levels in food and drinking water. The risk assessment took into consideration the relative contribution of exposure to boron from background sources and the pesticidal uses. In this approach, uses with exposure estimates that are in the range of

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potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

background levels from environmental sources were considered to be acceptable.

Potential exposure to borates may occur through the dermal and inhalation routes, when handling and applying antisapstain and joinery products containing borates or by handling the treated wood. When assessing health risks, two key factors are considered: the levels at which no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

Disodium octaborate tetrahydrate is considered toxicologically equivalent to other borates (borax, boric acid, anhydrous borax and borax pentahydrate). Inorganic borates are usually present as boric acid in the body. Most of the available toxicology data for borates is from studies using borax and boric acid.

In laboratory animals, both borax and boric acid were of low toxicity via the oral and dermal routes. Boric acid was of moderate toxicity via the inhalation route. Borax was severely irritating to the eyes and non-irritating to the skin, whereas boric acid was mildly irritating to the eyes and minimally irritating to the skin. No studies were available for either compound to assess their potential to cause allergic skin reactions.

Risks in Residential and Other Non-Occupational Environments

Non-occupational risks are not of concern.

There are currently no registered residential uses of boron antisapstain and joinery products. As such, a risk assessment for a residential handler was not required.

Occupational Risks to Mixer/Loader/Applicator and Postapplication Workers

Occupational risks are not of concern when used according to the revised label directions.

Health risks to handlers are not of concern for all scenarios. Based on the updated personal protective equipment (PPE) required as a result of the ERP for Antisapstain Chemicals (see Section 3.4.3 of the science evaluation), health risk estimates associated with mixing, loading, and applying and during handling of treated wood and joinery products exceeded target dermal margins of exposure (MOEs) and are not of concern. Inhalation exposure was shown to be very low for the majority of workers and is mitigated by the use of a NIOSH-respirator for specific job tasks where there is potential for inhalation exposure, as described in the ERP. Current product labels that do not include all of the required elements of the personal protective equipment will be updated to conform to the ERP.

Postapplication risks are not of concern.

Postapplication exposure through contact with dried wood is not anticipated as antisapstains are designed to prevent the growth of staining fungi in freshly cut lumber during storage and transit and not for long-term wood protection in residential or commercial areas. Similarly, exposure to consumers from contact with treated wood is also considered to be minimal.

Joinery wood is intended for use in millwork, window and door frames and other above ground non-structural decorative exterior wood such as soffits and fascia. Significant human exposure is not expected for this type of wood.

No health risks of concern were identified for workers handling freshly treated wood (wet or dry) in the sawmill. Since this type of exposure is expected to be greater than for workers or bystanders handling treated wood or joinery products after they have left the sawmill, postapplication health risks are not of concern.

Environmental Considerations

What Happens When Boron Is Introduced Into the Environment?

When used as an antisapstain according to the revised label directions, boron is not expected to pose risks of concern to the environment.

When boron (present as disodium octaborate tetrahydrate) is used as an antisapstain chemical, it may enter the environment if newly treated wood is exposed to rain. Boron may reach the aquatic environment if any rainwater containing the chemical is permitted to run-off from the treatment facility and its wood storage areas into nearby waterbodies. Very little exposure to land organisms and their habitats from wood treatment facilities is expected.

Boron is naturally present in the environment as borates, in certain types of rocks and soil, and does not break down further. It is released to the environment by weathering processes and is a component of ocean water. It is, therefore, widely distributed in nature. Plants require boron as an essential nutrient in small amounts and take it up from the soil. Boron mixes readily in water and can move easily through soils with low pH and moderately easily in soils with high pH. If boron is released into the air from water or moist surfaces, it would not persist in the atmosphere as it would be removed by rain. Boron is not expected to accumulate in the tissues of organisms. Boron is not very toxic to most aquatic organisms and when used according to the label directions, boron is not expected to pose risks of concern to freshwater invertebrates, freshwater fish, freshwater algae, amphibians, and marine fish.

Treated wood joinery products are not subject to significant leaching. Any leaching of joinery preservative that does occur, should be limited to the area around the building in which they were installed. Therefore, due to limited environmental exposure, no quantitative environmental risk assessment was conducted for the joinery uses of boron. Furthermore, as most joinery active ingredients are also antisapstain active ingredients, the environmental risk assessment for the antisapstain use of boron would be expected to cover any environmental risks posed by joinery

products.

Value Considerations

What is the Value of Boron in Antisapstain Treatment?

Boron is one of several active ingredients currently registered in Canada for use in antisapstain products. Antisapstain products are wood preservatives used to prevent the growth of staining fungi in freshly cut lumber. These pigmented fungi consume the readily available sugars and starches as they grow throughout the sapwood. While these sapstain fungi do not reduce the strength of the wood, the aesthetic damage done can result in significant economic losses in terms of the lumber being unmarketable or reduced in value.

What is the Value of Boron in Joinery Treatment?

Boron is one of five active ingredients currently registered in Canada for use in joinery products. Joinery products are wood preservatives used to treat products that have been machined or milled, such as window frames or doors. While these window frames and doors tend to be sheltered from excessive rains, they are still susceptible to fungal decay. Treatment with joinery products containing boron inhibits the growth of decay fungi and extends the service life of wooden joinery components.

Proposed Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. Following these directions is required by law. As a result of the re-evaluation of the antisapstain and joinery uses of boron, the PMRA is proposing further risk-reduction measures in addition to those already identified on boron product labels.

Additional Key Risk Reduction Measures

Human Health

To protect workers, additional general hygiene statements and personal protective equipment are required on all boron antisapstain and joinery product labels conforming to the ERP.

Environment

To minimize the amount of boron entering aquatic environments, wood treatment facilities using boron antisapstains are to be equipped with drip pads (where wood is allowed to sit for a short drying period immediately after treatment) that are roofed and paved.

Precautionary label statements are required to indicate directions to prevent runoff from treatment facilities to waterbodies.

Next Steps

Before making a final re-evaluation decision on the antisapstain and joinery uses of boron, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on boron. The PMRA will then publish a Re-evaluation Decision that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA response to these comments.

Science Evaluation

1.0 Introduction

Boron is registered in Canada for the control of a broad range of insects and fungi in structures, wood and wood products as well as a material preservative of paints and coatings, plastics and rubber. Boron inhibits reproduction of fungi by acting on the general metabolism, and acts as a stomach poison in insects.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

A review of the chemistry was previously conducted as part of the re-evaluation of the non-antisapstain uses of boric acid and its salts (PRVD2012-03 and RVD2016-01).

2.1 Identity of the Technical Grade Active Ingredient and the Physical and Chemical Properties of the Technical Grade Active Ingredient

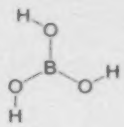
Active substance:	Disodium octaborate tetrahydrate
Function:	Wood preservative
Chemical name:	
IUPAC:	Disodium octaborate tetrahydrate
CAS:	Boron sodium oxide ($B_8Na_2O_{13}$), tetrahydrate
CAS Number:	12280-03-4
Molecular Formula:	$Na_2B_8O_{13}X4H_2O$
Molecular Mass:	412.52
Structural Formula:	$Na_2OX4(B_2O_3)X4H_2O$
Pest Control Product Number:	24739
Purity of Technical Grade Active Ingredient:	98% min.

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

Physical and Chemical Properties of Disodium Octaborate Tetrahydrate

Property	Result
Vapour pressure	Not required for a salt
Ultraviolet (UV)/visible spectrum	The product has no UV chromophores
Solubility in water	Temperature (°C) / Solubility (%w) 0 / 2.4 20 / 9.5 50 / 32.0
n-Octanol/water partition coefficient	Not applicable for an inorganic compound
Dissociation constant	Not provided

Active substance: Boric (or boracic) acid
Function: Insecticide, wood preservative
Chemical name:
IUPAC: Boric acid
CAS: Boric acid (H_3BO_3)
CAS Number: 10043-35-3
Molecular Formula: H_3BO_3
Molecular Mass: 61.83
Structural Formula:



Pest Control Product Number: 18292
Purity of Technical Active Ingredient: 100% nominal

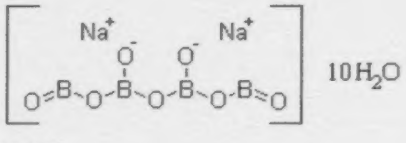
Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

Physical and Chemical Properties of Boric Acid

Property	Result
Vapour pressure at 20EC	346 Pa
Ultraviolet (UV)/visible spectrum	The product has no UV chromophores
Solubility in water	Temperature (°C) / Solubility (%w) 0 / 2.52 20 / 4.72 25 / 5.78 100 / 27.53
n-Octanol/water partition coefficient	Not applicable for an inorganic compound
Dissociation constant	$K = 7.3 \times 10^{-10}$

Active substance: Borax
Function: Fungicide, herbicide, insecticide, wood preservative

Chemical name:
IUPAC: Disodium tetraborate decahydrate
CAS: Borax (B4Na2O7.10H2O)
CAS Number: 1303-96-4
Molecular Formula: $Na_2B_4O_7X10H_2O$
Molecular Mass: 381.4
Structural Formula:



Pest Control Product Number: 18607
Purity of Technical Grade Active Ingredient: 100% minimum

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

Physical and Chemical Properties of Borax

Property	Result
Vapour pressure	Not required for a salt
Ultraviolet (UV)/visible spectrum	The product has no UV chromophores
Solubility in water at 20EC	4.71 g/100 mL
n-Octanol/water partition coefficient	Not applicable for an inorganic compound
Dissociation constant	Not provided

2.3 Description of Registered Boron Uses

Appendix I lists the antisapstain and joinery products containing boron that are registered under the authority of the *Pest Control Products Act*.

Currently, there are three sources of technical grade active ingredients and two end use products registered with boron, both of which contain DDAC as a co-biocide in the formulated end use products. An antisapstain product is applied to freshly-cut wood by dipping or spraying to achieve short-term protection against staining fungi. Joinery products may be applied by dipping, spraying, double vacuum treatment or flow/flood coating.

3.0 Impact on Human and Animal Health

3.1 Toxicology Summary

A review of the toxicity studies conducted with boric acid was previously conducted as part of the re-evaluation of the non-antisapstain uses of boric acid and its salts (PRVD2012-03 and RVD2016-01). A summary of the previously published information is presented below.

Disodium octaborate tetrahydrate is considered toxicologically equivalent to other borates (borax, boric acid, anhydrous borax and borax pentahydrate). Inorganic borates are usually present as boric acid in the body. Most of the available toxicology data for borates is from studies using borax and boric acid.

Borates are readily absorbed from the gastrointestinal tract. Distribution is uniform across most tissues, with higher levels found in the bone and fat than in other tissues. Greater than 90% of boric acid is eliminated via the urine within 96 hours of administration. Humans clear boron 3-4 times slower than the rat.

Acute toxicity data indicated that both borax and boric acid were of low toxicity via the oral route in rats and via the dermal route in rabbits. Boric acid was of moderate toxicity via the inhalation route of exposure in rats. In rabbits, borax was severely irritating to the eyes and non-irritating to the skin whereas boric acid was mildly irritating to the eyes and minimally irritating to the skin. No dermal sensitization studies were available for either compound.

The primary toxic effect noted in all species (mouse, rat and dog) in short- and long-term studies was on the testes (small testicles, tubular atrophy, arrest of spermatogenesis), with the dog being the most sensitive and the mouse the least sensitive species. There was a lack of detailed reporting on female reproductive organs. Effects at higher doses included mortality, decreased body weight gain, a general increase in clinical observations and effects on the skin. The dog also showed an increase in solid epithelial nests in the thyroid, which are considered to be pre-neoplastic lesions.

There were no adequate oncogenicity studies to fully assess the potential carcinogenic effects of boron. The three chronic toxicity studies were considered supplemental because of insufficient data reporting. Boron compounds were classified by the US EPA in 1994 as Group D; not classifiable as to human carcinogenicity. Genotoxicity studies using boric acid, including studies in bacteria, mammalian cells and mice in vivo, were negative.

In both the borax and boric acid reproduction toxicity studies in rats, the primary target organs were the testis (atrophy) and ovary (congested, cystic). No litters were produced by the high dose animals for either compound. When treated females were mated with control males, either no pups (boric acid) or very few pups (borax) were produced, indicating that exposure to these compounds resulted in decreased fertility in the female rat. A reproduction toxicity study with boric acid in mice showed decreases in fertility and body weight gain. Males had lower testicular weights, sperm concentration, and sperm count. In addition, males had increased testicular atrophy and abnormal sperm.

Several developmental toxicity studies with boric acid in the rat showed effects, including malformations, in the absence of maternal toxicity. Increased incidences of variations were noted at all dose levels. In rabbit developmental toxicity studies with boric acid, agenesis of the gallbladder occurred at maternally non-toxic doses. At maternally toxic doses, increased resorptions and cardiovascular effects were noted. Mice showed rib variations similar to those observed in the rat, but in the presence of maternal toxicity.

A recent comprehensive review of the epidemiology information related to boron has been conducted by the European Chemical Agency (ECHA, 2014) and Health Canada's HECSB (2016). Both reviews agree that available epidemiology information is of insufficient quality to select points of departure for risk assessment due to study limitations, including a limited evaluation of health endpoints. The ECHA report noted that available epidemiological studies addressed effects of exposure to inorganic borates in general, rather than focusing specifically on potential reproductive effects in humans. A decreased male:female sex ratio was the most common finding in human studies, and a lower Y:X ratio in sperm cells was reported in boron exposed workers. Although no significant adverse effects on reproduction or reproductive outcome were reported in workers or highly exposed populations, all epidemiological studies

exhibited methodological deficiencies (ECHA 2010, 2014). Furthermore, boron causes testicular histopathology in many animal species, with dogs as the most sensitive species. Although human studies demonstrated less overt toxicity than animal studies, human exposure levels were lower than those assessed in animal studies. Thus, epidemiological studies in humans were considered insufficient to demonstrate the absence of an adverse effect on fertility.

3.1.1 *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in and around homes or schools, the Pest Control Products Act (PCPA) requires the application of an additional 10-fold factor to threshold effects to take into account completeness of the data with respect to the exposure of and toxicity to infants and children, and potential prenatal and postnatal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

The toxicity database for boron contains both unpublished and published studies. Although the database is extensive, including two reproduction studies and several developmental studies, the unpublished studies are dated and do not meet current standards. Both the borax and boric acid reproduction toxicity studies in rats had considerable deficiencies including the lack of a detailed examination of the ovaries. While the testes were the primary target, when treated females were mated with control males, either no pups (boric acid) or very few pups (borax) were produced, indicating that exposure to these compounds also resulted in decreased fertility in the female rat. No litters were produced at high-doses. In a mouse reproduction toxicity study with boric acid, fertility was decreased and was primarily related to testicular toxicity. No litters were produced at the highest dose tested.

Published developmental toxicity studies in the rat showed increased sensitivity of the young. In the absence of overt maternal toxicity, foetuses had decreased body-weight gain, increased resorptions, and incidences of cleft sterna, agenesis of rib XIII, short rib XIII, wavy ribs, enlarged lateral ventricles of the brain, cardiovascular defects, hydrocephaly, short curly tail, anophthalmia and microphthalmia. The developmental rabbit toxicity study also showed sensitivity of the young with agenesis of the gallbladder being observed at a non-maternally toxic dose.

As previously stated, the current database for boron is very dated and does not meet current standards. However concerns for database uncertainties have been addressed with the application of an additional 3-fold uncertainty factor. Concerns for the observed pre- and post-natal toxicity are tempered by the fact that the dose-response in the rat developmental toxicity studies is well characterized, and the dose selected for the overall risk assessment is 4.5-fold lower than the NOAEL for malformations noted in the developmental rat toxicity study. Thus, based on these considerations, the PCPA factor was reduced to 1-fold.

3.2 Determination of Acceptable Daily Intake

Not applicable for antisapstain or joinery use.

3.3 Determination of Acute Reference Dose

Not applicable for antisapstain or joinery use.

3.4 Occupational and Non-Occupational Exposure and Risk Assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive sub-population. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

3.4.1 Toxicological Endpoint Selection for Occupational Risk Assessment

Occupational exposure to boric acid is characterized as intermittent long-term in duration and is predominately by the dermal route.

Long-term dermal endpoint
For long-term dermal exposure, a benchmark dose level (BMDL) of 2.90 mg/kg bw/day from the two 90-day dog toxicity studies was chosen for use in risk assessment. This BMDL was based on testicular weight. A target MOE of 300 was selected, which included standard uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variation. An additional 3-fold for database uncertainty was applied since it is likely that histological changes in testes would occur at a dose below those at which testicular weight are noted. This endpoint selection is considered protective of sensitive subpopulations, providing a margin of greater than 1300 to the NOAEL of 13.6 mg/kg bw/day for the malformation of cleft sterna noted in the rat developmental toxicity study. This margin addresses any concerns noted in the PCPA Hazard Characterization section that are relevant to the worker population. As such, no additional factor is required.

Table 3.4.1 Toxicology Endpoints for Use in Health Risk Assessment for Boron

Exposure Scenario	Study	Point of Departure and Endpoint	Target MOE
Long-term dermal	90-day dog dietary toxicity	(BMDL) of 2.90 mg/kg bw/day	300
Cancer	A cancer assessment was not required.		

3.4.2 ermal Absorption

A dermal absorption value of 10% was used in estimating the systemic dose from dermal exposure of boron for the risk assessment (RVD2016-01).

3.4.3 Occupational Exposure and Risk Assessment

Workers can be exposed to the antisapstain chemical boron while treating wood, handling treated wood and during clean-up, maintenance and repair activities.

The Sapstain Industry Group conducted passive dosimetry worker exposure studies to measure the potential exposure of sawmill workers that are exposed to antisapstain chemicals. The

complete study was divided into four phases: Phase I identified an appropriate surrogate chemical; Phase II monitored workers to determine job tasks with a potential for exposure to antisapstain chemicals (handling wet treated lumber, handling dry treated lumber, maintenance (including clean-up) and operating diptanks); Phase III measured workers exposure to those job tasks; and Phase IV measured worker's exposure following the implementation of a Product Stewardship and Exposure Reduction Program (ERP) for the job tasks that demonstrated the highest exposure during Phase III. The workers with the highest potential for exposure included clean-up and maintenance workers and pilers handling freshly treated wood. The ERP also identified areas in sawmills that would benefit from additional mitigation measures to reduce antisapstain chemical exposure, including engineering controls for application systems, instruction on safe handling procedures and proper personal protective equipment, and education on the health and safety properties of the antisapstain chemicals. The ERP was shown to reduce exposure for workers handling antisapstain chemicals.

Exposure to workers in a joinery mill is not expected to be underestimated by the Sapstain Industry Group antisapstain exposure study, which measured exposure during treatment by diptank and spraybox systems and while handling treated wood.

3.4.3.1 Occupational Antisapstain and Joinery Exposure and Risk Assessment

Workers can be exposed to boron while treating wood, handling treated wood and during clean-up, maintenance and repair activities. Exposure is expected to be long-term in duration and to occur primarily via the dermal route. Inhalation exposure was demonstrated to be very low for the majority of worker activities in the Phase III of the Sapstain Industry Group study and was not assessed during Phase IV. In addition, a NIOSH-respirator is required during clean-up, maintenance and repairs, and if working in areas that are not well ventilated, in order to reduce potential inhalation exposure as defined in the ERP.

Dermal exposure was estimated by combining the unit exposure values from the surrogate antisapstain worker exposure study with the amount of product handled per day and the dermal absorption value. Exposure was normalized to mg/kg bw/day by using 80 kg adult body weight.

The results of the health risk assessment for sawmill workers exposed to antisapstain or joinery products containing boron are shown in Table 3.4.3.1. Calculated MOEs exceeded the target MOE and no health risks of concern were identified for sawmill workers wearing the appropriate personal protective equipment as outlined in Appendix III.

Table 3.4.3.1: Boron Exposure Assessment for Sawmill Workers Exposed to Antisapstain and Joinery Products.

Tasks	Unit Exposure (µg/mg/mL)	Max Rate [1] (mg/mL)	Daily Exposure [2] (mg/kg bw/day)	MOE [3]
SIG Phase IV				
Pilers	493.7	12.48	0.007702	377
Clean-up Crew	203.1	12.48	0.003168	915
Maintenance Workers	401.4	12.48	0.006262	463

MOE = Margin of exposure

[1] The maximum treatment solution rates of all boron products is shown as the most conservative scenario.

[2] Daily Exposure = Unit Exposure (µg/mg/mL) * Max Rate * Dermal Absorption (10%) / Body Weight (80 kg)

[3] Dermal MOEs are based on an oral NOAEL of 2.90 mg/kg bw/day. Target MOE is 300. MOE = NOAEL / Daily Exposure.

3.4.4 Postapplication Worker Exposure and Risk Assessment

Postapplication exposure (for wood that has left the sawmill) is not anticipated, as antisapstains are designed to prevent the growth of staining fungi in freshly cut lumber during storage and transit and not for long-term wood protection in residential or commercial areas.

Joinery wood is intended for use in window and door frames and other above ground non-structural decorative exterior wood such as soffits and fascia. Additionally, joinery wood is often painted or covered with vinyl or aluminium or other material prior to being sold in the market. Significant human post-application exposure is not expected for this type of wood.

Furthermore, no health risks of concern were identified for workers handling freshly treated wood (wet or dry) in the sawmill whose exposure is expected to be greater than for workers handling of treated wood or joinery products after it has left the sawmill.

3.4.5 Non-Occupational Exposure and Risk Assessment

Non-occupational or residential risk assessment involves estimating risks to the general population, including children and youths, during or after pesticide application. There are no registered domestic class antisapstain or joinery products for boron. Residential exposure to individuals contacting wood treated with boron for antisapstain or joinery uses is not expected to result in health risks of concern.

3.4.6 Bystander Exposure

Bystander exposure is not anticipated, as boron containing antisapstain products are designed to prevent the growth of staining fungi in freshly cut lumber during storage and transit and not for long-term wood protection in residential or commercial areas.

Joinery wood is intended for use in window and door frames and other above ground non-structural decorative exterior wood such as soffits and fascia. Additionally, joinery wood is often painted or covered with vinyl or aluminium or other material prior to being sold in the market. Significant human exposure is not expected for this type of wood.

Furthermore, no health risks of concern were identified for workers handling freshly treated wood (wet or dry) in the sawmill whose exposure is expected to be greater than for bystanders handling treated wood or joinery products after it has left the sawmill.

Therefore, health risks to bystanders are not of concern.

3.5 Incident Reports Related to Health

Since April 2007, registrants have been required by law to report pesticide incidents to the PMRA that are related to their products. In addition, the general public, medical community, government and non-governmental organizations are able to report pesticide incidents directly to the PMRA. As of 27 October 2016, no health related incident reports specific to disodium octaborate tetrahydrate have been submitted to the PMRA.

3.6 Cumulative Assessment

Cumulative assessment takes into consideration non-occupational exposures (exposure via dietary, drinking water and residential use) to multiple pesticides that share a common mechanism of toxicity. As there are no domestic class registrations for boron as an antisapstain, and residential exposure to joinery-type products is anticipated to be minimal, a cumulative assessment is not required for these uses.

4.0 Impact on the Environment

Treated wood joinery products are not subject to significant leaching. The treated window frames and doors are either clad with protective aluminium or vinyl, or are top coated with paint or varnish. The finished windows and doors are installed above-ground in buildings that are generally designed to minimize contact with rain. Any leaching of joinery preservative that does occur, should be limited to the area around the building in which they were installed. Therefore, due to limited environmental exposure, no quantitative environmental risk assessment was conducted for the joinery uses of boron. Furthermore, as most joinery active ingredients are also antisapstain active ingredients, the environmental risk assessment for the antisapstain use of boron would be expected to cover any environmental risks posed by joinery products.

4.1 Fate and Behaviour in the Environment

Boron, as a metalloid chemical element, is not found in nature but is commonly found associated with other elements in the form of borate minerals, such as borax, borate and kernite. Boron (borate)-containing minerals are present in sedimentary rock, coal, shale and some soils. Boron is, therefore, naturally released into the environment through weathering processes. Other anthropogenic sources include fertilizers, pesticides and wastewater discharge.

Through its use as an antisapstain, boron (as disodium octaborate tetrahydrate) may enter the environment when it leaches from treated wood that has come into contact with water. Plants will take up boron from the soil in small amounts as it is an essential nutrient for plant growth and function.

The chemical (and toxicological) properties of boron, as borax pentahydrate, borax, boric acid, and other borates (e.g., disodium octaborate tetrahydrate), are expected to be similar on a mol boron/litre equivalent basis when dissolved in water or biological fluids at the same pH and low concentration. Boric acid is a very weak acid, with a pKa of 9.15, and therefore boric acid and the sodium borates exist predominantly as undissociated boric acid [$B(OH)_3$] in dilute aqueous solution below pH 7. Boron does not transform in water, soil, or air, or by microbial processes and, thus, is not expected to breakdown further in the environment.

Boron dissolves readily in water. The mobility of boron is somewhat pH dependent and it can move easily through soils with low pH and moderately easily in soils with high pH. Boron can, therefore, be expected to move to groundwater, particularly in light-textured soils. Boron is not expected to be released into the air from water or moist surfaces as a result of its high solubility in water. Atmospheric emissions of borates and boric acid in particulate and vapour form occur as a result of volatilization from the sea and volcanic activity. Boron is not expected to persist in the atmosphere as, due to its high water solubility, it would be removed by rain. Boron is taken up easily by mammals via ingestion and inhalation, but is not expected to accumulate in the tissues of organisms as it depurates from tissues rapidly. Boron (present as boric acid) has a low potential for partitioning into the sediment of aquatic systems under neutral and acidic conditions.

Data on the physicochemical properties of boron-containing compounds are presented in Appendix II, Table 1. Data on the fate and behaviour of boron in the environment are presented in Appendix II, Table 2.

4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide in the environment.

Environmental exposure from chemicals used to treat wood may result from two scenarios: runoff from wood treatment facilities to adjacent waterbodies, and direct leaching from treated wood in-use. Antisapstain products are designed for short-term protection of wood, primarily during its storage and transit, and for wood that is not expected to be in direct contact with soil or water during its use, such as in construction of above-ground components of various structures. Therefore, only an assessment of the potential environmental exposure from treatment facilities was considered to be relevant for antisapstain products.

At wood treatment facilities using antisapstain products, these chemicals may enter the environment when freshly treated wood is exposed to precipitation (primarily rainwater). Although the wood treatment process itself generally occurs in enclosed areas, immediately after the treatment the wood needs to sit for a short period of time to allow excess treatment solution to drip off the freshly-treated wood and for the wood to dry. This initial drying process is to take place outside on a drip pad that is roofed and paved. This minimizes the exposure of the treated wood to rain, while the paved surface aids in containing the drippings from the wood and channeling any excess chemicals to the appropriate receptacles for recycling or disposal. However, once the treated wood is dry, it is stored at the treatment facility until shipment to retailers and may be exposed to rain. Therefore, there is a potential that when used as an antisapstain, boron may enter the environment through leaching from the treated wood during storage at wood treatment facilities.

Exposure of terrestrial organisms to boron within the vicinity of these storage areas is expected to be negligible. Therefore, the risk to terrestrial organisms was not considered further in the risk assessment. Exposure to aquatic habitats is possible if boron leaches from stored, treated wood at treatment facilities and runs off to adjacent waterbodies.

The EECs of boron resulting from this use are based on selected exposure scenarios (Appendix II, Table 3), developed from the OECD Revised Emission Scenario Document for Wood Preservatives. Scenario selection was based on the following considerations:

- Boron is to be applied only by dipping (including immersion) or automated spraying (large plant / small plant) at treatment facilities.
- As boron is not expected to volatilize, EECs in air are expected to be negligible. EECs for this compartment are not required.
- Exposure of non-target organisms in the terrestrial environment is expected to be minimal.
- Environmental exposure to these products when the wood is in use is expected to be limited.
- Treatment facilities, including the drip pad for initial drying of treated wood, consist mostly of paved and roofed areas, except for longer-term storage, so leaching of boron from treated wood to soil is expected to be limited to in and around the facilities.
- Boron may enter the aquatic environment through leaching from treated wood stored at treatment facilities followed by run-off to nearby waterbodies (either freshwater or marine).

4.2.1 Risks to Aquatic Organisms

The exposure scenario for freshwater and estuarine organisms considers surface run-off into adjacent waterbodies from treatment plants using automated spraying (small plant, scenario 1; large plant, scenario 2) and dipping (scenario 3) product application methods. Conservative scenarios were used in the assessment. Specifically, it was assumed that the storage areas were uncovered and unprotected, 100% of the pesticide leached during the storage period, and that 50% of the rainwater ran directly into an adjacent surface water body. Further details for all exposure scenarios are presented in Appendix II, Table 3.

For the OECD scenarios, EECs are derived from the specific scenario parameters identified in Appendix II, Table 3 in combination with the deposition rate of the chemical as stated on the label (Appendix II, Table 4). For each scenario, EECs are representative of a daily average taken over the course of the storage period and consider that 100% of the pesticide leaches during that time.

Ecotoxicology information includes acute and chronic toxicity data for various groups of organisms from aquatic habitats (freshwater and marine) including invertebrates, vertebrates, and plants. A summary of the available aquatic toxicity data for boron is presented in Appendix II, Table 5. Aquatic toxicity values used for this assessment are summarized in Appendix II, Tables 6, and 7. As previously indicated, the toxicological properties of boron, as borax pentahydrate, borax, boric acid, and other borates (disodium octaborate tetrahydrate), are expected to be similar on a mol boron/litre equivalent basis when dissolved in water or biological fluids at the same pH and low concentration. Therefore, toxicity data for various boron-containing substances (borates and boric acid) were considered to be appropriate for this assessment.

For characterizing acute risk, acute toxicity values (for example, LC_{50} and EC_{50}) are multiplied by an uncertainty factor. The uncertainty factor is used to account for differences in inter- and intra-species sensitivity as well as varying protection goals (for example, community, population, individual). Thus, the magnitude of the uncertainty factor depends on the group of organisms that are being evaluated (for example 0.1 for fish, 0.5 for aquatic invertebrates). When assessing chronic risk, the NOEC or NOEL is used and an uncertainty factor is not applied.

A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the RQ is then compared to the level of concern (LOC). If the screening level RQ is below the LOC (LOC=1 for aquatic organisms), the risk is considered negligible and no further risk characterization is necessary. If the screening level RQ is equal to or greater than the LOC, then further characterization of the risk is required. Calculated EECs and RQs for freshwater and marine organisms are located in Appendix II, Table 6 and Table 7, respectively.

Freshwater Invertebrates: The risk quotient values for acute and chronic toxicity to freshwater invertebrates did not exceed the LOC for all scenarios. The use of boron is not expected to pose an acute or chronic risk to freshwater invertebrates.

Freshwater Fish: The risk quotient values for acute and chronic toxicity to freshwater fish did not exceed the LOC for all scenarios. The use of boron is not expected to pose an acute or chronic risk to freshwater fish.

Amphibians: The risk quotient values for chronic toxicity to amphibians did not exceed the LOC for all scenarios. The use of boron is not expected to pose a chronic risk to amphibians.

Freshwater Algae: The risk quotient values for acute toxicity to freshwater algae did not exceed the LOC for all scenarios. The use of boron is not expected to pose an acute risk to freshwater algae.

Marine Fish: The risk quotient values for acute toxicity to marine fish did not exceed the LOC for all scenarios. The use of boron is not expected to pose an acute risk to marine fish.

4.2.2 Overall Summary

When used as an antisapstain according to the revised label directions, boron is not expected to pose risks of concern to the environment. Boron has the potential to leach from wood at treatment facilities and subsequently run-off to aquatic environments. Precautionary label statements include directions to prevent surface runoff water from wood freshly treated with boron from reaching aquatic systems. (Appendix III)

4.2.3 Incident Reports Related to the Environment

There were no environmental incidents involving disodium octaborate tetrahydrate in the PMRA database as of October 27, 2016. A review of US incidents in the EIIS database (1992 to 2015) was also conducted. There were no environment incidents involving disodium octaborate tetrahydrate in the database.

5.0 Value

Antisapstains

Boron has value as one of several antisapstain active ingredients for controlling sapstain. The current active ingredients have replaced older antisapstain chemistries based on chlorophenates, which were phased-out in the 1980's for this use due to health and environmental concerns.

The application rates of antisapstain products are expressed both as treatment solution concentrations (%) and as the deposition rate in the treated wood (for example, µg a.i. per cm^2 wood). They are applied to freshly-cut wood in saw mills by dipping or spraying to achieve a short-term protection of several months. An alternative to antisapstain treatment is kiln-drying of the wood. However, some freshly cut lumber may still require antisapstain treatment while it is stored prior to kiln drying.

Joinery

Boron has value as one of several joinery active ingredients to protect millwork. The current active ingredients have replaced older joinery chemistries based on tributyltin and organic mercury-based products, which were discontinued in the 1990's due to health and environmental concerns. Joinery products are typically applied by dip and spray, but may also be applied to wood with flood coating or double vacuum treatment. The application rates of joinery products are expressed as treatment solution concentrations (%) and as either a deposition rate (µg a.i. per cm^2 wood surface) or a retention rate (kg a.i. per m^3 wood volume) in the treated wood.

6.0 Pest Control Product Policy Considerations

6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e., persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, boron was assessed in accordance with the PMRA Regulatory Directive DIR99-03[4] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Boron does not meet TSMP Track 1 criteria, and is not considered a TSMP Track 1 substance. See Appendix II, Table 8 for comparison with Track 1 criteria.

6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[5] The list is used as described in the PMRA Notice of Intent NOI2005-01[6] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02,[7] and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Boron does not contain any contaminants of health or environmental concern identified in the *Canada Gazette*.

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4 DIR99-03, The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy

5 Canada Gazette, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and in the order amending this list in the Canada Gazette, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.

6 NOI2005-01, List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern under the New Pest Control Products Act.

7 DIR2006-02, PMRA Formulants Policy.

- The end-use products F2 Concentrate T2154 Liquid Microbiocide and Antiblu F2 Concentrate T2154 Liquid Microbiocide do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

The use of formulants in registered pest control products is assessed on an ongoing basis through PMRA formulant initiatives and Regulatory Directive DIR2006-02.[8]

7.0 Proposed Re-evaluation Decision

The PMRA is proposing that antisapstain and joinery uses of products containing boron are acceptable for continued registration with additional risk-reduction measures to protect human health and the environment. The proposed mitigation measures are presented in Appendix III. No additional data are being requested at this time.

[8] DIR2006-02, PMRA Formulants Policy.

List of Abbreviations

a.i.	active ingredient
B	boron
BAF	bioaccumulation factor
BCF	bioconcentration factor
BMDL	benchmark dose level
d	day(s)
CEPA	Canadian Environmental Protection Act
bw	body weight
DDAC	didecyldimethylammonium chloride
cm	centimetre(s)
EC_{50}	effective concentration on 50% of the population
ECHA	European Chemical Agency
EEC	estimated environmental concentration
ERP	Exposure Reduction Program
g	gram(s)
h	hour(s)
HECSB	Healthy Environments and Consumer Safety Branch
i.e.	*id est*
kg	kilogram(s)
L	litre(s)
LC_{50}	lethal concentration 50%
LOC	level of concern
m	meter(s)
mg	milligram(s)
mL	millilitre(s)
mm Hg	millimetre(s) of mercury
MOE	margin of exposure
mPa	millipascal
NIOSH	National Institute for Occupational Safety and Health
N/A	not applicable
NOAEL	no observable adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
OECD	Organization for Economic Cooperation and Development
PCPA	Pest Control Product Act
PMRA	Pest Management Regulatory Agency
s	second
RQ	risk quotient

SIG	Sapstain Industry Group
TCMTB	2-(thiocyanomethylthio) benzothiazole
TSMP	Toxic Substances Management Policy
US EPA	United States Environmental Protection Agency
UV	ultraviolet
µg	microgram(s)

Appendix I

Table 1 Antisapstain and Joinery Boron Products Currently Registered

Active	Technical Grade Active Ingredient Sources		End-Use Products	
	Registration Number	Product Name	Registration Number	Product Name
Boron	24739	Octabor Technical	21939	F2 Concentrate T2154 Liquid Microbiocide
	18292	20 Mule Team Boric Acid Technical	27632	Antiblu F2 Concentrate T2154 Liquid Microbiocide
	18607	20 Mule Team Boric Acid Technical		

Appendix II

Table 1 Summary of Physicochemical Properties of Boric Acid and its Sodium Salts

Compound	Type of study	Value	Comments
Boric Acid	Solubility	13 g/L	Very Soluble (PMRA# 2644341)
Sodium tetraborate decahydrate (borax decahydrate)	Solubility	47 g/L	Very Soluble (PMRA# 2644341)
Sodium tetraborate pentahydrate (borax pentahydrate)	Solubility	35.9 g/L	Very Soluble (PMRA# 2644341)
Disodium octaborate tetrahydrate	Solubility	95 g/L	Very Soluble (PMRA# 2644341)
Boric Acid	Vapour Pressure	$< 10^{-4}$ mm Hg < 133 mPa	High volatility (PMRA# 2644341)
Sodium tetraborate decahydrate (borax decahydrate)	Vapour Pressure	$< 10^{-6}$ mm Hg < 1.33 mPa	Intermediate volatility (PMRA# 2644341)
Sodium tetraborate pentahydrate (borax pentahydrate)	Vapour Pressure	$< 10^{-6}$ mm Hg < 1.33 mPa	Intermediate volatility (PMRA# 2644341)
Sodium tetraborate (anhydrous borax)	Vapour Pressure	$< 10^{-6}$ mm Hg < 1.33 mPa	Intermediate volatility (PMRA# 2644341)
Sodium metaborate	Vapour Pressure	$< 10^{-6}$ mm Hg < 1.33 mPa	Intermediate volatility (PMRA# 2644341)
Boric Acid	Henry's Law Constant 1/H	3.84×10^{5} (calculated)	@ 20°C Not volatile from water and moist soil
Boric Acid	Dissociation constant (pK_a)	9.14	PMRA# 2644341
Boric Acid	Octanol-Water Partition Coefficient, log K_{OW}	0.175	PMRA# 2644341
Boric Acid	UV absorption spectrum in aqueous buffered solution λ=190-400 nm	No data	

Table 2 Fate and Behaviour of Boron in the Environment

Property	Test substance	Value	Transformation products	Comments	Reference
Abiotic transformation					
Hydrolysis	Boron	N/A	N/A	Boron (as borate and boric acid) does not break down	N/A
Phototransformation	Boron	N/A	N/A	Boron (as borate and boric acid) does not break down	N/A
Biotransformation					
Biotransformation in soil and water	Boron	N/A	N/A	Boron (as borate and boric acid) does not break down	N/A
Mobility					
Adsorption, K_d	Boron	< 1 ml/g	N/A	Highly mobile. Mobility is dependent on pH of soils. High potential for mobility in soils with lower pH.	PMRA# 2644341; PMRA# 2644339
Bioconcentration/bioaccumulation					
Bioconcentration in marine and freshwater plants, fish, and invertebrates	Sodium metaborate	BCF: <100	N/A	Did not bioconcentrate in large amounts in fish under the test conditions of the study.	PMRA# 1173841
Bioconcentration in Pacific oysters and juvenile Sockeye salmon	Sodium metaborate	Depuration to background boron concentrations occurred within 71 days	N/A	No evidence of bioconcentration found.	PMRA# 1173841

Table 3 Scenarios considered for the risk assessment

Scenario	Description	Details
Scenario for industrial preventive treatment		
	Runoff from storage of treated wood	
1	***Automated spraying (small plant)***	Surface area of the storage place: 79 m^2 Exposed surface of wood: 11 $m^2_{wood}/m^2_{storage\ area}$ Duration of storage: 3 d Rain fraction reaching water: 0.5 Flow rate of creek/river: 0.3 m^3s^{-1}
2	***Automated spraying (large plant)***	Surface area of the storage place: 790 m^2 Exposed surface of wood: 11 $m^2_{wood}/m^2_{storage\ area}$ Duration of storage: 3 d Rain fraction reaching water: 0.5 Flow rate of creek/river: 0.3 m^3s^{-1}
3	***Dipping/Immersion***	Surface area of the storage place: 700 m^2 Exposed surface of wood: 11 $m^2_{wood}/m^2_{storage\ area}$ Duration of storage: 14 d Rain fraction reaching water: 0.5 Flow rate of creek/river: 0.3 m^3s^{-1}

Table 4 Amount of Boron Leached from Freshly Treated Wood

Scenario	Deposition rate (µg/m^2)[a]	Surface area of the storage place (m^2)	Exposed surface of wood ($m^2_{wood}/m^2_{storage\ area}$)	Storage Period (d)	Amount of boron leached (kg/d)[b,c]
Automated spraying (small plant)	309 000	79	11	3	0.09
Automated spraying (large plant)	309 000	790	11	3	0.90
Dipping/Immersion	309 000	700	11	14	0.17

[a] Highest deposition rate of boron from all antisapstain products currently registered by the PMRA, calculated by VRD.
[b] Amount of boron leached = Deposition rate * Surface area of the storage place * Exposed surface of wood / Storage period.
[c] Emissions from a storage facility are considered stable over time and assume that 100% of the pesticide leaches during the storage period.

Table 5 Toxicity of Boron to Non-Target Aquatic Species

Organism	Exposure	Test substance	Endpoint value (mg B/L)	Degree of toxicity[1]	Reference
Freshwater species					
Freshwater invertebrates					
Daphnia magna	48-h LC_{50}	Boric acid	133	Practically non toxic	PMRA# 2644337
Daphnia magna	48-h LC_{50}	Boric acid	226	Practically non toxic	PMRA# 1249390
Daphnia magna	21-d NOEC	Boric acid	6.4	Not applicable	PMRA# 2644337
Daphnia magna	21-d NOEC	Boric acid	6	Not applicable	PMRA# 1249390
Freshwater fish					
Rainbow Trout (*Oncorhynchus mykiss*)	48-h LC_{50}	Boron	339	Practically non toxic	Alabaster *et al.*, 1957 in PMRA# 1249390
Rainbow Trout (*Oncorhynchus mykiss*) embryo-larval stages	28-d NOEC	Boric acid	0.5[2]	Not applicable	calculated from data in PMRA# 2644334
Rainbow Trout (*Oncorhynchus*	32-d NOEC	Boric acid	0.103[3]	Not applicable	calculated from data originating in Birge

Organism	Exposure	Test substance	Endpoint value (mg B/L)	Degree of toxicity[1]	Reference
mykiss) embryo-larval stages					and Black, 1984, taken from PMRA# 2644344
Rainbow Trout (*Oncorhynchus mykiss*) embryo-larval stages	28-d NOEC	Boric acid	0.11	Not applicable	PMRA# 2644344 in PMRA# 1173830
Rainbow Trout (*Oncorhynchus mykiss*) embryo-larval stages	28-d NOEC	Borax	9.63	Not applicable	PMRA# 2644344 in PMRA# 1173830
Rainbow Trout (*Oncorhynchus mykiss*) embryo-larval stages	28-d NOEC	Borax	0.96	Not applicable	PMRA# 2644344 in PMRA# 1173830
Rainbow Trout (*Oncorhynchus mykiss*) early life stages	36-d NOEC	Boric acid	0.75	Not applicable	Procter and Gamble, 1979 (unpublished) in PMRA# 1173830
Fathead minnow (*Pimephales promelas*) eggs and fry	30-d NOEC	Boric acid	14	Not applicable	Procter and Gamble, 1979 (unpublished) in PMRA# 1173830
Fathead minnow (*Pimephales promelas*) eggs and fry	60-d NOEC	Boric acid	24	Not applicable	Procter and Gamble, 1979 (unpublished) in PMRA# 1173830
Channel catfish (*Ictalurus punctatus*) embryo-larval stages	9-d NOEC	Boric acid	1.01	Not applicable	PMRA# 2644344 in PMRA# 1173830
Channel catfish (*Ictalurus punctatus*) embryo-larval stages	9-d NOEC	Boric acid	0.75	Not applicable	PMRA# 2644344 in PMRA# 1173830
Channel catfish (*Ictalurus punctatus*) embryo-larval stages	9-d NOEC	Borax	9.0	Not applicable	PMRA# 2644344 in PMRA# 1173830
Channel catfish (*Ictalurus punctatus*) embryo-larval stages	9-d NOEC	Borax	0.49	Not applicable	PMRA# 2644344 in PMRA# 1173830
Goldfish (*Carassius auratus*) embryo-larval stages	7-d NOEC	Boric acid	9.2	Not applicable	PMRA# 2644344 in PMRA# 1173830
Goldfish (*Carassius auratus*) embryo-larval stages	7-d NOEC	Boric acid	6.8	Not applicable	PMRA# 2644344 in PMRA# 1173830
Goldfish (*Carassius auratus*) embryo-larval stages	7-d NOEC	Borax	26.5	Not applicable	PMRA# 2644344 in PMRA# 1173830
Goldfish (*Carassius auratus*) embryo-larval stages	7-d NOEC	Borax	8.53	Not applicable	PMRA# 2644344 in PMRA# 1173830
Freshwater algae					
Green algae (*Scenedesmus subspicatus*)	72-h EC_{50}	Borax	34	Slightly toxic	Guhl, 1996 (German) in PMRA# 2644342
Amphibians					
Fowlers toad (*Anaxyrus fowleri*) embryo-larval stage	7-d NOEC	Boric acid	48.7	Not applicable	PMRA# 2644344 in PMRA# 1173830
Fowlers toad	7-d NOEC	Boric acid	22.3	Not applicable	PMRA# 2644344 in

Organism	Exposure	Test substance	Endpoint value (mg B/L)	Degree of toxicity[1]	Reference
(*Anaxyrus fowleri*) embryo-larval stage					PMRA# 1173830
Leopard Frog (*Rana pipiens*) embryo-larval stage	7-d NOEC	Boric acid	32.5	Not applicable	PMRA# 2644344 in PMRA# 1173830
Leopard Frog (*Rana pipiens*) embryo-larval stage	7-d NOEC	Boric acid	45.7	Not applicable	PMRA# 2644344 in PMRA# 1173830
Leopard Frog (*Rana pipiens*) embryo-larval stage	7-d NOEC	Borax	7.04	Not applicable	PMRA# 2644344 in PMRA# 1173830
Marine species					
Marine fish					
Common Dab (*Limanda limanda*)	24-h LC_{50}	Sodium metaborate	88.3	Slightly toxic	Taylor *et al.*,1985, in PMRA# 1173830
Common Dab (*Limanda limanda*)	72-h LC_{50}	Sodium metaborate	75.7	Slightly toxic	Taylor *et al.*,1985, in PMRA# 1173830
Common Dab (*Limanda limanda*)	96-h LC_{50}	Sodium metaborate	74	Slightly toxic	Taylor *et al.*,1985, in PMRA# 1173830
Coho Salmon (*Oncorhynchus kisutch*)	283-h LC_{50}	Sodium metaborate	113	Practically non toxic	PMRA# 1173841
Coho Salmon (*Oncorhynchus kisutch*) Early life stage	283-h LC_{50}[4]	Sodium metaborate	12.2	Slightly toxic	PMRA# 1173841
Coho Salmon (*Oncorhynchus kisutch*) Early life stage	96-h LC_{50}[5]	Sodium metaborate	40	Slightly toxic	PMRA# 1173841

[1] US EPA classification when available
[2] NOEC calculated from data in PMRA# 2644334
[3] NOEC calculated using data generated by Birge and Black, 1984, cited in PMRA# 2645034
[4] Endpoint not used in risk assessment as the study duration is too long to be considered an acute study and therefore an LC_{50} value is not appropriate
[5] Endpoint not used in risk assessment as the study was carried out with young coho salmon in salt water which is not representative of their natural habitat at this life stage

Table 6 Expected Environmental Concentrations (EECs) and Risk Quotients (RQs) for Freshwater Organisms Based on Storage of Treated Wood (Surface Runoff from Treatment Facilities).

Organism	Species Uncertainty Factor	Endpoint[1]				1-d EEC[2] (mg a.i./L)	RQ[3]
Storage after automated spraying (small plant)							
Daphnia magna	1/2	48-h LC_{50}	=	66.5	mg a.i./L	0.0035	<0.001
		21-d NOEC	=	6.0	mg a.i./L	0.0035	0.001
Rainbow trout	1/10	48-h LC_{50}	=	33.9	mg a.i./L	0.0035	<0.001
		NOEC	=	0.103	mg a.i./L	0.0035	0.034
Green algae	1/2	72-h EC_{50}	=	16	mg a.i./L	0.0035	<0.001
Leopard frog		7-d NOEC	=	7.04	mg a.i./L	0.0035	<0.001
Storage after automated spraying (large plant)							
Daphnia magna	1/2	48-h LC_{50}	=	66.5	mg a.i./L	0.0345	0.001
		21-d NOEC	=	6.0	mg a.i./L	0.0345	0.006
Rainbow trout	1/10	48-h LC_{50}	=	33.9	mg a.i./L	0.0345	0.001
		NOEC	=	0.103	mg a.i./L	0.0345	0.335
Green algae	1/2	72-h EC_{50}	=	16	mg a.i./L	0.0345	0.002
Leopard frog		7-d NOEC	=	7.04	mg a.i./L	0.0345	0.005
Storage after dip/immersion							
Daphnia magna	1/2	48-h LC_{50}	=	66.5	mg a.i./L	0.0066	<0.001
		21-d NOEC	=	6.0	mg a.i./L	0.0066	0.001
Rainbow trout	1/10	48-h LC_{50}	=	33.9	mg a.i./L	0.0066	<0.001
		NOEC	=	0.103	mg a.i./L	0.0066	0.064
Green algae	1/2	72-h EC_{50}	=	16	mg a.i./L	0.0066	<0.001
Leopard frog		7-d NOEC	=	7.04	mg a.i./L	0.0066	0.001

[1]Endpoints used in the acute exposure risk assessment are derived by multiplying the EC_{50} or LC_{50} from the appropriate laboratory study by the species uncertainty factor.
[2]Expected Environmental Concentration (EEC) = amount of boron leached per day (Table 4) / flow rate of a creek or river (Table 3). EECs are calculated on a per day basis.
[3]Risk Quotient (RQ) = exposure/toxicity. RQ > 1 (in bold) indicates exceedance of LOC (Level Of Concern).

Table 7 Expected Environmental Concentrations (EECs) and Risk Quotients (RQs) for Marine Organisms Based on Storage Of Treated Wood (Surface Runoff from Treatment Facilities)

Organism	Species Uncertainty Factor	Endpoint[1]	1-d EEC[2] (mg a.i./L)	RQ[3]
Storage after automated spraying (small plant)				
Common Dab	1/10	24-h LC_{50} = 7.4 mg a.i./L	0.0035	<0.001
Storage after automated spraying (large plant)				
Common Dab	1/10	24-h LC_{50} = 7.4 mg a.i./L	0.0345	0.005
Storage after dip/immersion				
Common Dab	1/10	24-h LC_{50} = 7.4 mg a.i./L	0.0066	0.001

[1]Endpoints used in the acute exposure risk assessment are derived by multiplying the EC_{50} or LC_{50} from the appropriate laboratory study by the species uncertainty factor.
[2]Expected Environmental Concentration (EEC) = amount of boron leached per day (Table 4) / flow rate of a creek or river (Table 3). EECs are calculated on a per day basis.
[3]Risk Quotient (RQ) = exposure/toxicity. RQ > 1 (in bold) indicates exceedance of LOC (Level Of Concern).

Table 8 Toxic Substances Management Policy Considerations – Comparison to TSMP Track 1 Criteria

TSMP Track 1 Criteria	TSMP Track 1 Criterion value		Active Ingredient Endpoints
Toxic or toxic equivalent according to the *Canadian Environmental Protection Act*[1]	Yes		Yes
Predominantly anthropogenic[2]	Yes		Yes
Persistence[3]:	Soil	Half-life ≥ 182 days	Boron (present in various forms) does not biotransform and is therefore classified as persistent in soil.
	Water	Half-life ≥ 182 days	Boron (present in various forms) does not biotransform and is therefore classified as persistent in water.
	Sediment	Half-life ≥ 365 days	Boron (present in various forms) does not biotransform and is therefore classified as persistent in sediment.
	Air	Half-life ≥ 2 days or evidence of long range transport	Boron (present in various forms) is released into the atmosphere through volcanic eruptions and evaporation from the ocean.
Bioaccumulation[4]	Log K_{OW} ≥ 5		Boron (present as boric acid): 0.175
	BCF ≥ 5000		< 100
	BAF ≥ 5000		Not available
Is the chemical a TSMP Track 1 substance (all four criteria must be met)?			No, does not meet TSMP Track 1 criteria.

[1] All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the CEPA toxicity criteria may be refined if required (in other words, all other TSMP criteria are met).
[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.
[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.
[4] Field data (for example, bioaccumulation factors [BAFs]) are preferred over laboratory data (for example, bioconcentration factors [BCFs]) which, in turn, are preferred over chemical properties (for example, log K_{OW}).

Appendix III Label Statements Proposed for Antisapstain and Joinery Products containing Boron

The label amendments proposed below do not include all label requirements for individual products, such as first aid statements, disposal statements, precautionary statements and protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

Proposed Statements to Protect Human Health

To protect workers, additional personal protective equipment is required on all boron antisapstain and joinery product labels. In order to conform to the ERP, the following statements are proposed to be included on the appropriate product labels in a section entitled **PRECAUTIONS**:

Antisapstain Product Labels

- Wear chemical-resistant coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, goggles or face shield, socks, and chemical-resistant footwear when handling the concentrate or during mixing/loading, application, clean-up, maintenance and repair activities.
- Use a NIOSH-respirator if the area is not well ventilated.
- Use a NIOSH-respirator during clean-up, maintenance and repair activities.
- When piling freshly treated lumber or if there is a potential for getting wet by the treating solution or by handling freshly treated lumber, wear chemical-resistant coveralls or a chemical-resistant apron over long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear.
- When working in the dip or spray area, wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and boots. Wear goggles or face shield if there is a possibility of splashing.
- Once dry, the treated wood can be handled with cotton or leather gloves.
- Wash hands and face before eating, drinking, smoking and using the toilet. Change clothes daily. Wash contaminated clothing separately from household laundry. Not for use or storage in or around the home. Clean contaminated equipment thoroughly prior to making welding repairs.

Joinery Product Labels

- Wear chemical-resistant coveralls over long-sleeved shirt and long pants, chemical-resistant gloves, goggles or face shield, socks, and chemical-resistant footwear when handling the concentrate or during mixing/loading, application, clean-up, maintenance and repair activities.
- Use a NIOSH-respirator if the area is not well ventilated.
- Use a NIOSH-respirator during clean-up, maintenance and repair activities and when opening pressure treatment cylinder doors.

- When handling freshly treated wood or if there is a potential for getting wet by the treating solution, wear chemical-resistant coveralls or a chemical-resistant apron over long-sleeved shirt and long pants, chemical-resistant gloves, socks and chemical-resistant footwear.
- When working in the application area, wear long-sleeved shirt, long pants, chemical-resistant gloves, socks and boots. Wear goggles or face shield if there is a possibility of splashing.
- Once dry, the treated wood can be handled with cotton or leather gloves.
- Wash hands and face before eating, drinking, smoking and using the toilet. Change clothes daily. Wash contaminated clothing separately from household laundry. Not for use or storage in or around the home. Clean contaminated equipment thoroughly prior to making welding repairs.

Proposed Environmental Statements

A. Environmental Label Statements Proposed for Technical Grade Active Ingredients: Octabor Technical, 20 Mule Team Boric Acid Technical, and 20 Mule Team Boric Acid Technical

I) **DISPOSAL**:

Canadian manufacturers should dispose of unwanted active ingredients and containers in accordance with municipal or provincial regulations. For additional details and clean-up of spills, contact the manufacturer or the provincial regulatory agency.

B. Label Statements Proposed for End-Use Products: F2 Concentrate T2154 Liquid Microbiocide and Antiblu F2 Concentrate T2154 Liquid Microbiocide

I) **DIRECTION FOR USE**:

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

This product is not to be used in circumstances that would cause or allow it to enter lakes, streams, ponds, estuaries, oceans or other waters in contravention of federal or provincial regulatory requirements. The requirements of applicable laws should be determined before using the product.

Dip tanks and drip aprons must be roofed, paved and drained to prevent dilution and loss of treatment solution.

Store treated lumber on a roofed drip pad until dripping has ceased. Slope lumber on the drip pad to expedite drainage and to ensure that no puddles remain on the surface of the wood. Manage drippage and other related wastes to prevent release in the environment.

DO NOT expose treated lumber to rains immediately after treatment.

For further information on storage, handling, and disposal of treated wood, contact the manufacturer of this product or the provincial regulatory agency.

II) **DISPOSAL**:

DO NOT reuse this container for any other purpose. This is a recyclable container, and is to be disposed of at a container collection site. Contact your local distributor/dealer or municipality for the location of the nearest collection site. Before taking the container to the collection site:

1. Triple- or pressure-rinse the empty container. Dispose of the rinsings in accordance with provincial requirements.

2. Make the empty, rinsed container unsuitable for further use.

   If there is no container collection site in your area, dispose of the container in accordance with provincial requirements.

   For information on disposal of unused, unwanted product, or in the case of a spill or spill clean-up, contact the manufacturer or the provincial regulatory agency.

List of References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT

Human Health

PMRA #	Reference
1188767	1999, Generic Anti-Sapstain Worker Exposure Study NP-1 Phase III Field Study, Measurement and Assessment of Dermal and Inhalation Exposures to Didecyldimethylammonium Chloride (DDAC) Used in the Protection of Cut Lumber (Phase III), Final Report, K.T. Bestari Et Al, October 25, 1999 [Antisapstain Products;SUBN.#97-0521;Submitted December 20, 1999;Volume 1 of 7], DACO: 5.1,5.6
1665704	2008, Final Report: Field Monitoring and Re-evaluation of Workers Dermal Exposures to Didecyldimethylammonium Chloride (DDAC) Used in the Protection of Cut Lumber, DACO: 5.4
1289169	2005, Exposure Reduction Program for Antisapstain Chemicals. Green Chain Pullers/Pilers and Cleanup Crew, DACO: 5.14
1726847	DACO: 5.6(A)_DOC Post Application: Passive Dosimetry Data Agricultural

Impact on the Environment

PMRA#	Reference
1173829	ECETOC. 1997. Ecotoxicology of Some Inorganic Borates. Special Report No 11. ISSN-0773-8072-11. European Center for Ecotoxicology and Toxicology of Chemicals. 99 p., DACO 9.1
1173830	Butterwick, L., N. De Oude, and K. Raymond. 1989. Safety Assessment of Boron in Aquatic and Terrestrial Environments. Ecotoxicology and Environmental Safety. V. 17, p. 339-371, DACO 9.1
1173833	Keren, R. and F.T. Bingham. 1985. Boron in Water, Soils and Plants. Advances In Soil Science. Vol. 1. p. 229-276, DACO 8.2.4.2
1173841	Thompson, J.A., J.C. Davis, and R.E. Drew. 1976. Toxicity Uptake and Survey Studies of Boron in the Marine Environment. Water Research. Vol. 10. p. 869 – 875, DACO 8.3.4

1173842 Hamilton, S. J. and R.H. Wiedmeyer. 1990. Concentrations of Boron, Molybdenum, and Selenium in Chinook Salmon. Transactions of the American Fisheries Society, 199, p. 500 – 510, DACO 8.3.4

1249390 Lewis, M.A. and L.C. Valentine. 1981. Acute and Chronic Toxicities of Boric Acid to Daphnia magna Straus. Bull. Environm. Contam. Toxicol. Vol. 27. p. 309-315, DACO 9.5.2.1

199151 US EPA. 1993. Boric Acid/Sodium Metaborate RED. Office of Prevention, Pesticides and Toxic Substances. 25 p, DACO 12.5

B. ADDITIONAL INFORMATION CONSIDERED

i) Published Information

Chemistry

PMRA #	Reference
2238832	Canada 2012, Proposed Re-evaluation Decision, Boric Acid and its Salts (Boron). PRVD2012-03

Human Health

PMRA #	Reference
2238832	Canada 2012, Proposed Re-evaluation Decision, Boric Acid and its Salts (Boron). PRVD2012-03
2662413	Canada 2016, Re-evaluation Decision, Boric Acid and its Salts (Boron). RVD2016-01
2690171	2016 Environment Canada, Health Canada Draft Screening Assessment: Boric Acid, its Salts and its Precursors Healthy Environments and Consumer Safety. July 23 2016. DACO12.5
2604858	European Chemicals Agency, 2014, Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of Boric Acid, DACO 12.5
2604855	2010, Proposal for identification of a substance as substance of very high concern (SVHC). Substance name: Boric acid. [ECHA] European Chemicals Agency Annex XV dossier. EC Number: 233-139-2/234-343-4. CAS RN: 10043-35-3/11113- 50-1. DACO 12.5

Environment

PMRA#	Reference
2644334	Birge, W. and J. Black. 1977. Sensitivity of Vertebrate Embryos to Boron Compounds. Report No. EPA 560/1-76-008. US Environmental Protection Agency. Washington, DACO 9.9
2644337	Gersich, F. 1984. Evaluation of a Static Renewal Chronic Toxicity Test Method for Daphnia Magna Straus Using Boric Acid. Env. Tox. Chem. V. 3. p. 89-94, DACO 9.9
2644339	Goldberg, S. 1997. Reactions of boron with soils. Plant and Soil. V. 193. p. 35-48, DACO 8.6
2644341	US EPA. 1993. Boric Acid and Its Sodium Salts, Reregistration Eligibility Document. Office of Prevention, Pesticides and Toxic Substances. 256 p, DACO 8.6
2644342	World Health Organisation. 1998. Environmental Health Criteria 204 Boron. United Nations Environment Programme, International Labour Organisation, International Programme on Chemical Safety. 122 p, DACO 8.6
2644344	Dyer, S.D. 2001. Determination of the aquatic $PNEC_{0.05}$ for boron. Chemosphere, 44, p. 369–376, DACO 9.9
2645034	Krahn, P.K. and R. Strub. 1990. Standard leaching test for antisapstain chemicals. Regional Program Report 90-10. Environment Canada, Pacific and Yukon Region, DACO 8.6
2647634	Organization for Economic Co-operation and Development (OECD) Environment Directorate. 2003, revised 2013. Revised Emission Scenario Document for Wood Preservatives, Series on Emission Scenario Documents No.2, DACO: 8.6